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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/732,360	12/07/2000	Hanan Polansky	SCI - 1	1705
26694	7590	03/15/2004	EXAMINER	
VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998			YU, MISOOK	
			ART UNIT	PAPER NUMBER

1642

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/732,360

Applicant(s)

POLANSKY, HANAN

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2003 and 09 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-45 and 51-64 is/are pending in the application.
- 4a) Of the above claim(s) 26-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: CRF Problem Report

DETAILED ACTION

Applicant amendments filed on 7/22/2003 and 10/09/2003 are acknowledged.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Election/Restrictions

This application contains claims 26-45 drawn to an invention nonelected with traverse in Paper No. 3. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 26-45 remain withdrawn from further consideration for reason of record.

The Listing of Claims filed on 10/09/2003 says that claims 51-64 are "(previously presented)". However, the prosecution history indicates claims 51-64 are presented with the amendment filed on 7/22/2003, therefore claims 51-64 are new to this Office action. Claims 26-45, and 51-64 are pending. The new claims 51-64, drawn to method determining **copy number of N-boxes** are under consideration.

Comply to Sequence Rule

Since sequence rule has not been complied thus far, the specification is still objected.

Claim Rejections - 35 USC § 112

The new claims 51-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 51-64 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: conclusion step linking the purpose stated in the preamble of the claims to active step of the claims.

The **rejection** of the now cancelled claims under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **applied to new claims 51-64**. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to method involving **assaying the copy number of the N-boxes in system** after a compound has been added.

Applicant argues at page 11 of the amendment filed 10/09/2003 that HIV has 2 copies of N-boxes; EBV has 20 copies; HTLV has 8; at page 14 of said amendment that the specification at page 137 teaches to measure copy number of viral DNA using real-time PCR. These arguments have been fully considered but found unpersuasive because the argument, with the specification at page 137, is not commensurate in scope of the claims because instantly claimed method is to measure which compound modifies (decreases) copy number of N-boxes, for example whether a compound changes EBV N-box from 20 copies to 10 copies. Instant invention is drawn to method to determine **the copy number of N-boxes**, not copy number of viral genome.

Claims 51-64 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection. The Office is unable to find support the limitation "**modulating a disease**", "the system includes a known copy number of **N-boxes**", "**modifies** the copy number" in the base claims of 51 and 60. The originally filed specification communicates that the invention is to method of identifying compound using assay capable of determining compounds **decreases foreign DNA N-boxes** in cells for the purposes of **treating adverse affects associated with a disruption of GABP's metabolic pathway**". The new limitations presented in the amendments after the first Office action broadens the scope of the invention the specification as originally filed.

Further, the Office is not able to find support for "**active N-boxes**" in claim 54.
What is active vs. inactive?

The Office is not able to find support for "the compound **modifies the copy number of N-boxes bound by a transcription complexes** in claim 55.

The rejection of claims (now all canceled) under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is **applied to new claims 51-59**. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is

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most nearly connected, to make and/or use the invention. The claims are interpreted as drawn to method of screening compounds to be used for treating in cancer as in new claim 56, atherosclerosis recited in new claim 57, osteoarthritis in claim 58, and obesity recited in new claim 59.

Applicant argues that new claims 51-64 have been submitted. The new claims center on copy number assays and require the presence of N-boxes. The requisite steps and conditions of the screening method are set forth. Operation of the screening method relative to a compound of interest is described in the specification. Copy number assays are well known in the art. Moreover, the specification provides multiple examples of these assays such that one of ordinary skill in art would be able to practice the claimed invention. These arguments have been fully considered but found unpersuasive because applicant's arguments are commensurate in scope of the claims. The full scope of the claims are drawn to method of finding something capable of modulating a disease (note the previous Office action mailed) and the specification fails to teach any compound that is screened using the instantly claimed method could accomplish the purpose stated in the preamble of the claims.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne C Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
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LARRY R. HELMS, PH.D.
PRIMARY EXAMINER